

**THE UNITED STATES PATENT AND TRADEMARK OFFICE  
BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES**

Applicants: Tuan Bui, et al.  
Appl. No.: 10/059,929  
Conf. No.: 8386  
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Title: SYSTEM AND METHOD FOR OPERATING MEDICAL DEVICES  
Art Unit: 3626  
Examiner: Dilek B. Cobanoglu  
Docket No.: 5807US (3712044-01098)

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**REPLY BRIEF**

Sir:

Appellants submit this Reply Brief in response to the Examiner's Answer dated October 18, 2010. This Appeal is taken from the Final Rejection in the Office Action dated April 16, 2010. This Reply Brief is accordingly timely filed.

Claims 1 to 191 are pending in the above-identified application and stand rejected. Therefore, Claims 1 to 191 are under appeal. A copy of the appealed claims is included in the Claims Appendix of Applicants' Appeal Brief.

**A. A prima facie case has not been made under 35 U.S.C. §102(e) that Claims 1 to 191 are unpatentable over United States Patent No. 6,790,198 to White et al. ("*White*").**

As explained in the Appeal Brief, one of the benefits of the claimed system is that bypassing computers at the patient location (e.g., having operating parameters sent directly from a central computer without manual healthcare provider interaction), along with other comparison steps discussed in detail below, helps eliminate human error. (See page 10, lines 21 to 27 of the application). The Examiner's Answer still fails to identify these advantageous steps in *White*.

*White* is generally directed to a wireless communication system between an IV medication infusion pump and a hospital information management system ("HIMS"). A transmitter is connected to the pump, which transmits a signal representing pre-selected pump operation characteristics to the HIMS. The HIMS includes a receiver configured to receive the signal and a processor capable of storing and displaying the pump operation characteristics. The pump is also configured to receive pump operation characteristics.

**1. Claims 1 to 20**

Claim 1, for example, includes determining if a second patient identifier (e.g., from a patient wristband) is equivalent to a third patient identifier (e.g., from a medication label) and sending a medication identifier to a first computer (e.g., a central hospital computer) *if the second patient identifier is equivalent to the third patient identifier*, and determining if the third patient identifier is equivalent to a first patient identifier (e.g., a patient identifier manually entered into the central hospital computer) and sending the operating parameter from the first computer to the medical device *if the third patient identifier is equivalent to the first patient identifier*, where the operating parameter does not pass through the second computer. The Examiner's Answer does not identify the claimed three-way cross check, as discussed below.

Referring to page 6 of the Examiner's Answer, the Examiner appears to rely on the following passage of *White* as disclosing the above steps, relying primarily on the below-emphasized language:

The IV pump 10 may receive a wireless signal indicating the appropriate instruction pumping characteristics for the IV fluid container that is connected to the IV pump 10 for the identified patient 20. Such infusion data and pumping characteristics will nevertheless need to be validated by the nurse in order to maintain the integrity of the system. For example, the nurse may enter the information from the IV fluid container identifying the medication, may also identify the patient, and may provide the nurse's identification consistent with authorization to administer medications to the patient. The pump operation data may be downloaded from the doctor's order, from the pharmacy instructions or from the HIMS 60. *For purposes of central administration control, the doctor's order and/or the pharmacy instructions may be wirelessly received at the HIMS and such order and instructions may be checked and corroborated with patient information and/or medical information stored in the HIMS for purposes of confirming proper administration to the patient.* (Column 8, line 55 to column 9, line 6) (emphasis added).

Nowhere does this passage refer to determining if *a second patient identifier* is equivalent to *a third patient identifier* and sending a medication identifier to a first computer *if the second patient identifier is equivalent to the third patient identifier*, and determining if *the third patient identifier* is equivalent to *a first patient identifier* and sending the operating parameter from the first computer to the medical device *if the third patient identifier is equivalent to the first patient identifier*, where the operating parameter does not pass through the second computer.

The Answer refers to the patient ID at column 4, line 46 of *White* as a first patient identifier but then jumps to an alternative embodiment, referring to the patient ID at column 13, lines 4 to 5 of *White*, as a second patient identifier and the patient identification field of a barcode label at column 13, line 13 of *White* as a third patient identifier. The above-emphasized disclosures from *White* not only improperly picks and chooses from different embodiments, the passages also make no reference whatsoever to: (i) the second embodiment in *White* referred to by the Examiner, (ii) to any specific patient identifier, (iii) to cross-checking specific patient identifiers as claimed, or (iv) to sending certain information *if* certain specific patient identifiers match as claimed.

Further, the Answer again fails to recognize that in all embodiments disclosed in *White*, a nurse manually verifies any instruction sent to or entered into the pump. In *White*, a nurse has to manually review each instruction and validates it prior to beginning the treatment. For example,

absent from the Answer's citation to columns 8 and 9 of *White* is the sentence following the above-emphasized disclosure, which states:

In that embodiment, *the nurse may activate wireless downloading of pump operation data from the HIMS 60 to IV pump 10*, as, for example, by wireless signal 67. (Column 9, lines 7 to 9) (emphasis added).

Other passages from *White* corroborate that a nurse has to manually review each instruction and validate the instruction prior to beginning the treatment:

- "Such infusion data and pumping characteristics will nevertheless need to be validated by the nurse, in order to maintain the integrity of the system" (column 8, lines 59 to 61)."
- In Fig. 5 of *White*, at box 79, the nurse validates that the instructions received by the pump are correct and begins the infusion.
- "The nurse may use a hand-held communication unit 98 to manually enter information from a label on an IV container. The nurse may transmit the instructional data to the IV pump and upon confirming the patient, medication and pumping data match, the nurse may initiate IV pumping (column 9, lines 35 to 40)."
- "Again, upon confirming the information loaded into the IV pump, the nurse may activate pumping operations (column 9, lines 57 and 58)."
- "If all of the required infusion information is validated by the nurse, then the infusion may be initiated according to the accurately scanned infusion information . . . (column 12, lines 24 to 27)."

The structure combined with the comparison features of claim 1 and the operating parameter not being sent through the second computer (i.e., a hand-held unit) help eliminate human error in the administration of a treatment to a patient. *White* does not disclose the automated nature and detailed checks of the claimed system and method, but rather, requires a nurse to verify all treatments and treatment parameters. For at least the above reasons, the rejection of Claims 1 to 20 as anticipated by *White* should be reversed.

Claims 21 to 191 provide substantially similar elements to those discussed above with respect to Claim 1 and the rejection of those claims should be reversed for the same and additional reasons discussed below.

## 2. Claims 21 to 35

For example, Claim 21 is directed to a system for operating a medical device including , the system comprising a first computer, the first computer designed to accept *a first patient identifier and an operating parameter for the medical device*; a second computer, the second computer designed to accept *a second patient identifier* from a first source, the second computer designed to accept a medication identifier from a second source, *the medication identifier including a third patient identifier*, where the second computer is designed to send the medication identifier to the first computer *if the second patient identifier and the third patient identifier are equivalent*; where the first computer is designed to send the operating parameter to the medical device *if the third patient identifier is equivalent to the first patient identifier*, where the operating parameter does not pass through the second computer. For the reasons discussed above, *White* clearly does not disclose the emphasized features.

## 3. Claims 36 to 40

Claim 36 is directed to a program for operating a medical device, the program stored on a computer readable medium, the program comprising logic for: accepting a first input from a first computer, the first input including *a first patient identifier and an operating parameter for the medical device*; accepting a second input from a second computer, the second input including a first portion and a second portion, the first portion coming from a first source, the first portion including *a second patient identifier*, the second portion coming from a second source, the second portion including a medication identifier, *the medication identifier including a third patient identifier*; sending the medication identifier to the first computer, *if the second patient identifier is equivalent to the third patient identifier*; and sending the operating parameter to the medical device, *if the third patient identifier is equivalent to the first patient identifier*, where the operating parameter does not pass through the second computer. For the reasons discussed above, *White* clearly does not disclose the emphasized features.

## 4. Claims 41 to 44

Claim 41 is directed to a system for operating a medical device, the system comprising means for accepting a first input at a central location, the first input including *a first patient identifier and an operating parameter for the medical device*; means for accepting a second input at a remote location, the second input including a first portion and a second portion, the

first portion coming from a first source, the first portion including *a second patient identifier*, the second portion coming from a second source, the second portion including a medication identifier, *the medication identifier including a third patient identifier*; means for sending the medication identifier to the central location, *if the second patient identifier is equivalent to the third patient identifier*; and means for sending the operating parameter to the medical device, *if the third patient identifier is equivalent to the first patient identifier*, where the operating parameter does not pass through a computer prior to being accepted by the medical device. For the reasons discussed above, *White* clearly does not disclose the emphasized features.

#### 5. Claims 45 to 61

Claim 45 is directed to a method for operating a medical device, the method comprising the steps of accepting a first input at a first computer, the first input including *a first patient identifier* and an operating parameter for the medical device; accepting a second input from a second computer, the second input associated with information derived from a device attached to a patient, *the second input including a second patient identifier*; accepting a third input from the second computer, the third input associated with information affixed to a medication container, the third input including a medication identifier, *the medication identifier including a third patient identifier*; and sending the operating parameter from the first computer to the medical device *if the first, second, and third patient identifiers are equivalent*, where the operating parameter is sent without passing through the second computer. For the reasons discussed above, *White* clearly does not disclose the emphasized features.

#### 6. Claims 62 to 66

Claim 62 is directed to a program for operating a medical device, the program stored on a computer readable medium, the program comprising logic for accepting a first input at a first computer, the first input including *a first patient identifier* and an operating parameter for the medical device; accepting a second input from a second computer, the second input associated with information derived from a device attached to a patient, the second input including *a second patient identifier*; accepting a third input from the second computer, the third input associated with a information affixed to a medication container, the third input including a medication identifier, *the medication identifier including a third patient identifier*; and sending the operating parameter from the first computer to the medical device *if the first, second, and third*

*patient identifiers are equivalent*, without passing through the second computer. For the reasons discussed above, *White* clearly does not disclose the emphasized features.

**7. Claims 67 to 114**

Claims 67 to 114 additionally provide that *a latest operating parameter* is compared to a first operating parameter. The latest operating parameter is provided to the medical device under certain conditions. *White* does not disclose or suggest such features.

Specifically, Claim 67 is directed to a method for operating a medical device, the method comprising the steps of inputting, at a central location, *a first patient identifier* and a first operating parameter for the medical device; inputting from a first source, at a remote location, *a second patient identifier*; inputting from a second source, at the remote location, a medication identifier, *the medication identifier including a third patient identifier*; sending the medication identifier to the central location, *if the third patient identifier is equivalent to the first patient identifier*; *finding a latest operating parameter at the central location, if the third patient identifier is equivalent to the first patient identifier*; and *sending a confirmation to the remote location, if the first operating parameter is equivalent to the latest operating parameter*; and *sending the latest operating parameter to the medical device, if the first operating parameter is equivalent to the latest operating parameter*.

Claim 87 is directed to a system for operating a medical device, the system comprising a first processor at a central location, the first processor designed to accept *a first patient identifier* and a first operating parameter for the medical device; and a second processor at a remote location, the second processor designed to accept *a second patient identifier* from a first source; the second processor designed to accept a medication identifier from a second source, *the medication identifier including a third patient identifier*, where the second processor is designed to *send the medication identifier to the central location, if the third patient identifier is equivalent to the first patient identifier*, where the first processor is designed to *find the latest operating parameter at the central location, if the third patient identifier is equivalent to the first patient identifier*, where the first processor is designed to *send a confirmation to the second processor, if the first operating parameter is equivalent to the latest operating parameter*, and where the first processor is designed to *send the latest operating parameter to*

*the medical device, if the first operating parameter is equivalent to the latest operating parameter.*

Claim 95 is directed to a program for operating a medical device, the program stored on a computer readable medium, the program comprising logic for accepting *a first patient identifier* and a first operating parameter for the medical device from an input device at a central location; accepting *a second patient identifier* from a first source, the first source at a remote location; accepting a medication identifier from a second source, the second source at the remote location, the medication identifier including *a third patient identifier*; *sending the medication identifier to the central location, if the third patient identifier is equivalent to the first patient identifier*; *finding a latest operating parameter, if the third patient identifier is equivalent to the first patient identifier*; *sending a confirmation to the remote location, if the first operating parameter is equivalent to the latest operating parameter*; and *sending the latest operating parameter to the medical device, if the first operating parameter is equivalent to the latest operating parameter.*

Claim 101 is directed to a method for operating a medical device, the method comprising the steps of storing medical treatment data in a memory associated with a fast processor, the medical treatment data including *a first patient identification data*, a first medication identification data, and a first plurality of medical device operating parameters, where the first plurality of medical device operating parameters is associated with the medical treatment data and the patient identification data; inputting second medication identification data into a second processor, where the second medication identification data is associated with medication to be administered to a patient, where the medical device is operably connected to the second processor; inputting *second patient identification data* into the second processor; sending the second medication identification data and the second patient identification data from the second processor to the first processor; *finding a latest plurality of medical device operating parameters in the memory associated with the first processor*; and *sending the latest plurality of medical device operating parameters to the second processor if a comparison of the first and second patient identifiers satisfies a first predetermined condition, and if a comparison of the first and second medication identification data satisfies a second predetermined condition*; *sending a confirmation to the second processor if the first plurality of operating parameters is*



*equivalent to the latest plurality of operating parameters; sending the latest plurality of operating parameters to the medical device if the first plurality of operating parameters is equivalent to the latest plurality of operating parameters.*

Claim 108 is directed to a program for operating a medical device, the program stored on a computer readable medium, the program comprising logic for: storing medical treatment data in a memory associated with a first processor, the medical treatment data including *a first patient identification data*, a first medication identification data, and a first plurality of medical device operating parameters, where the first plurality of medical device operating parameters is associated with the medical treatment data and the patient identification data; accepting a second medication identification data into a second processor, where the second medication identification data is associated with medication to be administered to a patient, where the medical device is operably connected to the second processor; accepting *a second patient identification data* into the second processor; sending the second medication identification data and the second patient identification data from the second processor to the first processor; *finding a latest plurality of medical device operating parameters in the memory associated with the first processor; sending the latest plurality of medical device operating parameters to the second processor if a comparison of the first and second patient identifiers satisfies a first predetermined condition, and if a comparison of the first and second medication identification data satisfies a second predetermined condition; sending a confirmation to the second processor if the first plurality of operating parameters is equivalent to the latest plurality of operating parameters; and sending the latest plurality of operating parameters to the medical device if the first plurality of operating parameters is equivalent to the latest plurality of operating parameters.*

The Examiner's Answer made no attempt to specifically identify any such disclosures in *White*, nor has the Examiner made any such attempt at any point during the prosecution of the present application. For this additional reason, the rejection of Claims 67 to 114 as anticipated by *White* should be reversed.

#### 8. Claims 115 to 145

Claim 115 is directed to a method for operating a medical device, the method comprising the steps of: inputting, at a central location, *a first patient identifier* and *a first operating*

*parameter* for the medical device; inputting *a second patient identifier* into a processor from a first source, the processor being at a remote location; inputting a medication identifier and *a second operating parameter* for the medical device into the processor, the medication identifier and a second operating parameter coming from a second source, the medication identifier including *a third patient identifier*; sending the medication identifier and the second operating parameter to the central location, *if the second patient identifier is equivalent to the third patient identifier*; sending the second operating parameter to the medical device without passing through the processor, *if the first and second operating parameters are equivalent and if the first and second patient identifiers are equivalent*.

Claim 133 is directed a system for operating a medical device, the system comprising: a computer at a central location, the computer designed to accept *a first patient identifier* and *a first operating parameter* for the medical device; a processor at a remote location, the processor designed to accept *a second patient identifier* from a first source; the processor designed to accept a medication identifier and *a second operating parameter* for the medical device from a second source, the medication identifier including *a third patient identifier*; where the processor sends the medication identifier and the second operating parameter to the computer, *if the second patient identifier is equivalent to the third patient identifier*, and where the computer sends the second operating parameter to the medical device without passing through the processor, *if the first and second operating parameters are equivalent and if the first and second patient identifiers are equivalent*.

Claim 141 is directed to a program for operating a medical device, the program stored on a computer readable medium, the program comprising logic for: accepting, at a central location, *a first patient identifier* and *a first operating parameter* for the medical device; accepting *a second patient identifier* into a processor from a first source at a remote location; accepting a medication identifier and *a second operating parameter* for the medical device at the remote location, the medication identifier and a second operating parameter coming from a second source, the medication identifier including *a third patient identifier*; sending the medication identifier and the second operating parameter to the central location, *if the second patient identifier is equivalent to the third patient identifier*; sending the second operating parameter to

the medical device without passing through the processor, *if the first and second operating parameters are equivalent and if the first and second patient identifiers are equivalent.*

*White* clearly does not disclose the cross check of patient identifiers of Claims 115, 133 and 141, for the reasons discussed above, nor does *White* disclose the emphasized comparison of *first and second operating parameters*. Further, again the Examiner's Answer made no attempt to specifically identify such a comparison of operating parameters, nor was any such attempt made at any point during the prosecution of the present application. Accordingly, the rejection of Claims 115 to 145 should be reversed.

#### **9. Claims 146 to 166**

Claim 146 includes the steps of reading a medication identifier at a remote location, the medication identifier including a second patient identifier and *a first medical device identifier*; reading *a second medical device identifier* at the remote location, the second medical device identifier being affixed to the medical device; and receiving an operating parameter for the medical device from a central location, *if a first patient identifier is equivalent to a second patient identifier*, and *if the medical device identifier and the second medical device identifier are equivalent.*

Claim 160 includes similar features. Specifically, Claim 160 is directed to a program for operating a medical device, the program stored on a computer readable medium, the program comprising logic for: reading *a first patient identifier* at a remote location, the first patient identifier being attached to a patient's body; reading a medication identifier at the remote location, the medication identifier including *a second patient identifier* and *a first medical device identifier*; reading *a second medical device identifier* at the remote location, the second medical device identifier being affixed to the medical device; and trigger the transmission of an operating parameter for the medical device from a central location to a medical device, *if the first patient identifier is equivalent to the second patient identifier*, and *if the medical device identifier and the second medical device identifier are equivalent.* *White* does not disclose or suggest such features. Again, the Examiner's Answer makes no attempt to specifically identify any such disclosure in *White*, nor was any such attempt made at any point during prosecution of the present application. Accordingly, the rejection of Claims 146 to 160 as anticipated by *White* should be reversed.

Claim 155 provides a digital assistant designed to trigger the transmission of an operating parameter for a medical device from a central location to the medical device, *if a first patient identifier is equivalent to a second patient identifier*. *White* does not disclose such a digital assistant. For this additional reason, the rejection of Claim 155 and dependent Claims 156 to 159 as anticipated by *White* should be reversed.

Claim 165 includes storing a first operating parameter at a central location, the first operating parameter associated with a first patient identifier; accepting a second operating parameter into a medical device, the medical device being at a remote location; accepting the first patient identifier into the medical device; sending the second operating parameter and the first patient identifier to the central location; and *sending an alarm to the remote location, if the first operating parameter is not equivalent to the second operating parameter*. [Emphasis added]. Claims 175 and 182 include similar claim language.

#### 10. Claims 175 to 191

Specifically, Claim 175 is directed to a system for operating a medical device, the system comprising: a computer at a central location, the computer designed to store *a first operating parameter*, the first operating parameter associated with *a first patient identifier*; a medical device having a processor and an input device, the input device designed to read *a second operating parameter* from a medication label, the input device designed to read the first patient identifier from a wristband using the input device, the medical device at a remote location, the processor designed to send the second operating parameter and the first patient identifier to the central location, where *the computer is designed to send an alarm to the remote location, if the first operating parameter is not equivalent to the second operating parameter*.

Claim 182 is directed to a program for operating a medical device, the program stored on a computer readable medium, the program comprising logic for: storing *a first operating parameter* at a central location, the first operating parameter associated with *a first patient identifier*; accepting *a second operating parameter* into a medical device, the medical device at a remote location; accepting the first patient identifier into the medical device; sending the second operating parameter and the first patient identifier to the central location; *sending an alarm to the remote location, if the first operating parameter is not equivalent to the second operating parameter*. *White* does not disclose the foregoing emphasized features. Further, the

Examiner's Answer was unable to specifically identify such features in *White* and nowhere at any point during prosecution of the present application were any such features identified. For this additional reason, the rejection of Claims 155, 175 and 182 and the claims depending therefrom as anticipated by *White* should be reversed.

**B. Conclusion.**

Appellants respectfully submit that the Answer has failed to establish that Claims 1 to 191 are unpatentable over *White*. Accordingly, Appellants respectfully submit that the obviousness rejections are erroneous in law and in fact and should therefore be reversed by this Board. The Director is authorized to charge any other fees that may be required, or to credit any overpayment to Deposit Account No. 02-1818.

Respectfully submitted,

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